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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,519	12/14/2001	Betty Wu	10255-028-999	3927
26161	7590	01/11/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/014,519	WU ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,12-14,16-19,21-23,25-30,32,33 and 35-44 is/are pending in the application.
- 4a) Of the above claim(s) 38-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9,12-14,16-19,21-23,25-30,32,33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claim 38 drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly submitted claims 39 – 44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The microfluidic devices, as recited in claims 1 and 16, do not require the incorporation of a multi-valve structure, as recited for the device in claim 39; The methodologies, as recited in claims 27 and 33, do not require the use of thermopneumatic actuation, as recited for the methodology in claim 40.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39 – 44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Allowable Subject Matter***

The indicated allowability of claim 30 is withdrawn in view of the reference to Lipshutz et al. (US 5,856,174). A rejection based upon the cited reference follows.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 – 29 and 32 – 37 have been considered, but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4, 9, 12 – 14, 16 – 19, 21 – 23, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al. (US 5,856,174).

Regarding claims 1 and 12, Lipshutz et al. anticipates a microfluidic apparatus comprising: a lysing zone or chamber; an associated thermopneumatic fluid pumping system; and vent structures within the chamber and channel network of the microfluidic apparatus (see col. 5, line 25 – col. 6, line 27; col. 13, line 47 – col. 14, line 34; col. 20, lines 37 – 46; col. 21, lines 19 – 25; col. 22, lines 49 – 67; col. 24, lines 11 – 33).

Regarding claim 2, this claim recitation is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Process limitations do not add patentability to a structure, which is not distinguished from the prior art.

Regarding claims 3 and 4, Lipshutz et al. teach the use of an electric field in performing cell lysis/extraction (see col. 5, lines 49 – 64). Furthermore, regarding claim 4, this claim recitation is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Process limitations do not add patentability to a structure, which is not distinguished from the prior art.

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Regarding claims 9 and 13, Lipshutz et al. teach the incorporation of a reduced or poorly wetting hydrophobic material associated with a vent structure to facilitate fluid flow control within the apparatus (see col. 17, lines 28 – 61).

Regarding claim 14, Lipshutz et al. teach the further incorporation of a valve associated with a vent (see col. 20, lines 37 – 46).

Regarding claims 16, 21, 23, 25 and 26, Lipshutz et al. anticipates a microfluidic apparatus comprising: a lysing zone or chamber; an associated thermopneumatic or gas actuation fluid pumping system; and a positioning element or vent structure, which further comprises a hydrophobic material for facilitating effective fluid flow control, within the chamber and channel network of the microfluidic apparatus (see col. 5, line 25 – col. 6, line 27; col. 13, line 47 – col. 14, line 34; col. 17, lines 28 – 65; col. 20, lines 37 – 46; col. 21, lines 19 – 25; col. 22, lines 49 – 67; col. 24, lines 11 – 33). Claim 16 also recites how the thermopneumatic gas actuator operates in preparing a microdroplet fluid sample. This claim recitation is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Process limitations do not add patentability to a structure, which is not distinguished from the prior art.

Regarding claims 17, 18, 19 and 25, the recitations of these claims also contain process or intended use limitations.

Regarding claim 18, Lipshutz et al. teach the use of an electric field in performing cell lysis/extraction (see col. 5, lines 49 – 64).

Regarding claim 22, Lipshutz et al. indicates that the microfluidic apparatus is fabricating as an integrated substrate body (see col. 13, line 47 – col. 16, line 18).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27 – 30, 32, 33 and 35 – 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. Regarding claims 27 – 30, 32, 33 and 35 – 37, as discussed above, Lipshutz et al. teach all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the the method recited in the instant claims upon the apparatus of Lipshutz et al. and Brody, as such is the intended operation of that apparatus.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700